Safety and Efficacy of the Percutaneous Transvenous Mitral Annuloplasty Device to Reduce Mitral Regurgitation.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28876

Source
NTR

Brief title
PTOLEMY

Health condition

Heart Failure
Mitral Regurgitation
Mitral valve disease
Mitral valve insufficiency
Hartfalen
Mitralisklepinsufficiëntie
Mitralisklep
Kleplijden

Sponsors and support

Primary sponsor: Viacor Inc. (Kate Stohlman)
Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

Percent of patients who remain free from device-related major adverse events:

- death

- myocardial infarction

- tamponade

- emergent cardiac surgery at 6 months.

Secondary outcome

- Percent of implanted patients who maintain a sustained 1 grade reduction in mitral regurgitation and reduction in mitral anterior posterior dimension at 6 months.

- Improvement of clinical symptoms of heart failure as defined by percent of implanted patients who exhibit one of the following:

* decrease in NYHA class, or increase in Minnesota Living with Heart Failure score, or increase in exercise capacity at 30 days and 6 months.

Study description

Study objective

Improvement in heart failure with moderate to severe mitral regurgitation using a percutaneously delivered implanted device

Study design

Post-procedural follow-up tup to 5 years.

Intervention

Patient is screened for study and given baseline assessments. Patient receives a diagnostic PTMA assessment and if responsive, receives a PTMA implant.

Contacts

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Eligibility criteria

Inclusion criteria

1. Symptomatic heart failure

2. Functional MR 2+ - 4+

3. LVEF < 45%

Exclusion criteria

1. MR of organic origins

2. Significant co-morbidities

Study design

Design

Study type:	Interventional
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-06-2006
Enrollment:	20
Type:	Actual

Ethics review

Positive opinion

Date:	20-05-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1278
NTR-old	NTR1324
Other	Belgian registration number : B7072006352
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
Please see under below link:
http://www.viacorinc.com/bibliography.html